

### **Amendments to the Claims**

This listing of claims will replace all prior versions and listings of claims in the application.

1-12 (cancelled).

13 (previously presented). A method for treating a bacterial infection in a patient, the method comprising:

administering to the patient in need thereof a therapeutically effective amount of a composition in solid form comprising amoxicillin and potassium clavulanate and comprising a first release phase and a second release phase;

the first release phase comprising potassium clavulanate and a first portion of the amoxicillin;

the second release phase comprising a second portion of amoxicillin, which is a pharmaceutically acceptable soluble salt of amoxicillin, and at least one pharmaceutically acceptable organic acid which are admixed in intimate contact at a ratio of from 20:1 to 1:2.

Claims 14-17 (cancelled).

18 (previously presented). A method according to claim 13 in which the bacterial infection is caused by at least one of the organisms *S. pneumoniae*, *H. influenzae*, and *M. catarrhalis*.

19-68 (cancelled).

69 (previously presented). A method according to claim 18 wherein the *S. pneumoniae* are Drug Resistant *S. pneumoniae* and Penicillin Resistant *S. pneumoniae* organisms.

70 (previously presented). A method according to claim 13 wherein the amount of amoxicillin in the first release phase is released upon exposure to an aqueous environment.

71 (previously presented). A method according to claim 13 wherein the ratio of the pharmaceutically acceptable soluble salt of amoxicillin to the at least one pharmaceutically acceptable organic acid in the second release phase is from about 2:1 to about 1:1.2.

72 (previously presented). A method according to claim 13 wherein the ratio of the amoxicillin in the first release phase to the amoxicillin in the second release phase is from about 3:1 to about 1:3.

73 (previously presented). A method according to claim 13 wherein the ratio of the amoxicillin in the first release phase to the amoxicillin in the second release phase is from about 2:1 to about 2:3.

74 (previously presented). A method according to claim 71 wherein the ratio of the amoxicillin in the first release phase to the amoxicillin in the second release phase is from about 2:1 to about 2:3.

75 (previously presented). A method according to claim 13 wherein the ratio of the amoxicillin in the first release phase to the amoxicillin in the second release phase is from about 3:2 to about 1:1.

76 (previously presented). A method according to claim 71 wherein the ratio of the amoxicillin in the first release phase to the amoxicillin in the second release phase is from about 3:2 to about 1:1.

77 (previously presented). A method according to claim 13 wherein the ratio of the amoxicillin in the first release phase to the amoxicillin in the second release phase is about 9:7.

78 (currently amended). A method according to claim 13 wherein the at least one pharmaceutically acceptable organic acid is selected from the group consisting of pharmaceutically acceptable monocarboxylic and polycarboxylic acids having from 2 to 25 carbon atoms, pharmaceutically acceptable monocyclic aryl and polycyclic aryl acids, and pharmaceutically acceptable monohydrogen and dihydrogen ~~[[ salts , or ]]~~ metal salts of multi-valent acids.

79 (currently amended). The method according to claim 78 wherein the at least one pharmaceutically acceptable organic acid is selected from the group consisting of pharmaceutically acceptable monocarboxylic acids having from 2 to 10 carbon atoms, and polycarboxylic acids having from 2 to 10 carbon atoms ~~and a metal salt thereof~~.

80 (currently amended). The method according to claim 71 wherein the at least one pharmaceutically acceptable organic acid is selected from pharmaceutically acceptable monocarboxylic acids having from 2 to 10 carbon atoms, [[and ]] or polycarboxylic acids having from 2 to 10 carbon atoms ~~and a metal salt thereof~~.

81 (currently amended). The method according to claim 75 wherein the at least one pharmaceutically acceptable organic acid is selected from pharmaceutically acceptable monocarboxylic acids having from 2 to 10 carbon atoms, ~~and~~ or polycarboxylic acids having from 2 to 10 carbon atoms ~~and a metal salt thereof~~.

82 (currently amended). A method according to claim 13 wherein the at least one pharmaceutically acceptable organic acid is selected from the group consisting of C<sub>(2-10)</sub> alkyl-

and C<sub>(2-10)</sub> alkenyl- carboxylic acids having one, two, or three carboxylic acid groups, and optionally at least one hydroxy substituent, and optionally at least one -CO group in the carbon chain.

83 (currently amended). A method according to claim 13 wherein the at least one pharmaceutically acceptable organic acid is selected from the group consisting of malonic acid, succinic acid, fumaric acid, maleic acid, adipic acid, lactic acid, levulinic acid, sorbic acid, tartaric acid, malic acid, ascorbic acid, citric acid, and an acidic salt thereof.

84 (currently amended). A method according to claim 71 wherein the at least one pharmaceutically acceptable organic acid is selected from the group consisting of malonic acid, succinic acid, fumaric acid, maleic acid, adipic acid, lactic acid, levulinic acid, sorbic acid, tartaric acid, malic acid, ascorbic acid, citric acid, and an acidic salt thereof.

85 (currently amended). A method according to claim 81 wherein the at least one pharmaceutically acceptable organic acid is selected from the group consisting of malonic acid, succinic acid, fumaric acid, maleic acid, adipic acid, lactic acid, levulinic acid, sorbic acid, tartaric acid, malic acid, ascorbic acid, citric acid, and an acidic salt thereof.

86 (previously presented). A method according to claim 13 wherein the at least one pharmaceutically acceptable organic acid is citric acid.

87 (previously presented). A method according to claim 71 wherein the at least one pharmaceutically acceptable organic acid is citric acid.

88 (previously presented). A method according to claim 75 wherein the at least one pharmaceutically acceptable organic acid is citric acid.

89 (previously presented). A method according to claim 88 wherein the citric acid is citric acid anhydrous.

90 (previously presented). A method according to claim 13 wherein the pharmaceutically acceptable soluble salt of amoxicillin is sodium amoxicillin.

91 (previously presented). A method according to claim 71 wherein the pharmaceutically acceptable soluble salt of amoxicillin is sodium amoxicillin.

92 (previously presented). A method according to claim 75 wherein the pharmaceutically acceptable soluble salt of amoxicillin is sodium amoxicillin.

93 (previously presented). A method according to claim 85 wherein the pharmaceutically acceptable soluble salt of amoxicillin is sodium amoxicillin.

94 (previously presented). A method according to claim 88 wherein the pharmaceutically acceptable soluble salt of amoxicillin is sodium amoxicillin.

95 (previously presented). A method according to claim 13 wherein the pharmaceutically acceptable soluble salt of amoxicillin is crystallized sodium amoxicillin.

96 (previously presented). A method according to claim 88 wherein the pharmaceutically acceptable soluble salt of amoxicillin is crystallized sodium amoxicillin.

97 (previously presented). A method according to claim 13 wherein the ratio of the amount of amoxicillin in the composition to the amount of potassium clavulanate is from about 2:1 to about 20:1.

98 (previously presented). A method according to claim 13 wherein the ratio of the amount of amoxicillin in the composition to the amount of potassium clavulanate is from about 12:1 to about 20:1.

99 (previously presented). A method according to claim 13 wherein the ratio of the amount of amoxicillin in the composition to the amount of potassium clavulanate is from about 14:1 to about 16:1.

100 (previously presented). A method according to claim 71 wherein the ratio of the amount of amoxicillin in the composition to the amount of potassium clavulanate is from about 14:1 to about 16:1.

101 (previously presented). A method according to claim 75 wherein the ratio of the amount of amoxicillin in the composition to the amount of potassium clavulanate is from about 14:1 to about 16:1.

102 (previously presented). A method according to claim 88 wherein the ratio of the amount of amoxicillin in the composition to the amount of potassium clavulanate is from about 14:1 to about 16:1.

103 (previously presented). A method according to claim 97 wherein the pharmaceutically acceptable soluble salt of amoxicillin is crystallized sodium amoxicillin and the at least one pharmaceutically acceptable organic acid is citric acid anhydrous.

104 (previously presented). A method according to claim 13 wherein all of the potassium clavulanate of the composition is present in the first release phase.

105 (previously presented). A method according to claim 84 wherein all of the potassium clavulanate of the composition is present in the first release phase.

106 (previously presented). A method according to claim 94 wherein all of the potassium clavulanate of the composition is present in the first release phase.

107 (previously presented). A method according to claim 13 wherein the first release phase comprises at least one pharmaceutically acceptable soluble salt of amoxicillin, amoxicillin trihydrate, or a mixture thereof.

108 (previously presented). A method according to claim 105 wherein the first release phase comprises at least one pharmaceutically acceptable soluble salt of amoxicillin, amoxicillin trihydrate, or a mixture thereof.

109 (previously presented). A method according to claim 13 wherein the amount of amoxicillin in the composition is from about 700 mg to about 2600 mg.

110 (previously presented). A method according to claim 99 wherein the amount of amoxicillin in the composition is from about 700 mg to about 2600 mg.

111 (previously presented). A method according to claim 13 wherein the amount of amoxicillin in the composition is from about 700 mg to about 1300 mg.

112 (previously presented). A method according to claim 99 wherein the amount of amoxicillin in the composition is from about 700 mg to about 1300 mg.

113 (previously presented). A method according to claim 106 wherein the amount of amoxicillin the composition is from about 700 mg to about 1300 mg.

114 (previously presented). A method according to claim 13 wherein the amount of amoxicillin in the composition is from about 950 mg to about 1300 mg.

115 (previously presented). A method according to claim 102 wherein the amount of amoxicillin in the composition is from about 950 mg to about 1300 mg.

116 (previously presented). A method according to claim 13 wherein the amount of amoxicillin in the composition is from about 1400 mg to about 2600 mg.

117 (previously presented). A method according to claim 102 wherein the amount of amoxicillin in the composition is from about 1400 mg to about 2600 mg.

118 (previously presented). A method according to claim 13 wherein the amount of amoxicillin in the composition is from about 1900 mg to about 2600 mg.

119 (previously presented). A method according to claim 106 wherein the amount of amoxicillin-in the composition is from about 1900 mg to about 2600 mg.



120 (previously presented). A method according to claim 13 wherein the amount of amoxicillin in the composition is about 1000 mg or about 2000 mg.

121 (currently amended). A method according to claim 108 wherein the amount of amoxicillin in the composition is about 1000 mg or about 2000 mg.

122 (previously presented). A method according to claim 13 wherein the amount of amoxicillin administered to the patient is about 2000 mg.

123 (previously presented). A method according to claim 13 wherein the amount of amoxicillin in the second release phase is from about 60% to about 80% by weight of the second release phase.

124 (previously presented). A method according to claim 105 wherein the amount of amoxicillin in the second release phase is from about 60% to about 80% by weight of the second release phase.

125 (previously presented). A method according to claim 119 wherein the amount of amoxicillin in the second release phase is from about 60% to about 80% by weight of the second release phase.

126 (previously presented). A method according to claim 113 wherein the amount of amoxicillin in the second release phase is from about 60% to about 80% by weight of the second release phase.

127 (previously presented). A method according to claim 13 wherein the amount of amoxicillin in the first release phase is 563 mg +/- 5% and the amount of amoxicillin in the second release phase is 438 mg +/- 5%.

128 (previously presented). A method according to claim 88 wherein the amount of amoxicillin in the first release phase is 563 mg +/- 5% and the amount of amoxicillin in the second release phase is 438 mg +/- 5%.

129 (previously presented). A method according to claim 103 wherein the amount of amoxicillin in the first release phase is 563 mg +/- 5% and the amount of amoxicillin in the second release phase is 438 mg +/- 5%.

130 (previously presented). A method according to claim 106 wherein the amount of amoxicillin in the first release phase is 563 mg +/- 5% and the amount of amoxicillin in the second release phase is 438 mg +/- 5%.

131 (previously presented). A method according to claim 13 wherein the first release phase and the second release phase of the solid form composition is divided into multiple dosage form units.

132 (previously presented). A method according to claim 110 wherein the first release phase and the second release phase of the solid form composition is divided into multiple dosage form units.

133 (previously presented). A method according to claim 116 wherein first release phase and the second release phase of the solid form composition is divided into multiple dosage form units.

134 (previously presented). A method according to claim 131 wherein the amoxicillin present in one of the multiple dosage form units is amoxicillin trihydrate.

135 (previously presented). A method according to claim 110 wherein the amoxicillin present in one of the multiple dosage form units is amoxicillin trihydrate.

136 (previously presented). A method according to claim 117 wherein the amoxicillin present in one of the multiple dosage form units is amoxicillin trihydrate.

137 (previously presented). A method according to claim 134 wherein the amoxicillin in the first release phase is amoxicillin trihydrate and the amoxicillin in the second release phase is a soluble salt of amoxicillin.

138 (previously presented). A method according to claim 106 wherein the first release and the second release phase of the solid form composition is divided into multiple dosage form units.

139 (previously presented). A method according to claim 117 wherein the first release and the second release phase of the solid form composition is divided into multiple dosage form units.

140 (previously presented). A method according to claim 125 wherein the first release and the second release phase of the solid form composition is divided into multiple dosage form units.

141 (previously presented). A method according to claim 13 wherein the composition is in the form of a compressed tablet.

142 (previously presented). A method according to claim 141 wherein the composition is in the form of a monolith tablet.

143 (previously presented). A method according to claim 74 wherein the composition is in the form of a compressed tablet.

144 (previously presented). A method according to claim 85 wherein the composition is in the form of a compressed tablet.

145 (previously presented). A method according to claim 93 wherein the composition is in the form of a compressed tablet.

146 (previously presented). A method according to claim 145 wherein the composition is in the form of a monolith tablet.

147 (previously presented). A method according to claim 103 wherein the composition is in the form of a compressed tablet.

148 (previously presented). A method according to claim 115 wherein the composition is in the form of a compressed tablet.

149 (previously presented). A method according to claim 130 wherein the composition is in the form of a compressed tablet.

150 (previously presented). A method according to claim 141 wherein the compressed tablet comprises at least two layers.

151 (previously presented). A method according to claim 144 wherein the compressed tablet comprises at least two layers.

152 (previously presented). A method according to claim 147 wherein the compressed tablet comprises at least two layers.

153 (previously presented). A method according to claim 143 wherein all of the first release phase is in a first layer and all of the second release phase is in a second layer.

154 (previously presented). A method according to claim 144 wherein all of the first release phase is in a first layer and all of the second release phase is in a second layer.

155 (previously presented). A method according to claim 145 wherein all of the first release phase is in a first layer and all of the second release phase is in a second layer.

156 (currently amended). A method according to claim 141 wherein the second release phase of the tablet further comprises at least one release retarding excipient which is selected from the group consisting of pH sensitive polymers, release-retarding polymers which exhibit swelling characteristics when in an aqueous environment, polymeric materials which exhibit gelling characteristics when in an aqueous environment, and polymeric materials which exhibit both swelling and gelling characteristics when in an aqueous environment.

157 (currently amended). A method according to claim 156 wherein the at least one release retarding gellable polymer is selected from the group consisting of methylcelluloses, carboxymethylcelluloses, low-molecular weight hydroxypropylmethylcelluloses, low-molecular weight polyvinylalcohols, polyoxyethyleneglycols, and noncross-linked polyvinylpyrrolidones.

158 (currently amended). A method according to claim 85 wherein the second release phase of the tablet further comprises at least one release retarding excipient which is selected from the group consisting of pH sensitive polymers, release-retarding polymers which exhibit swelling characteristics when in an aqueous environment, polymeric materials which exhibit gelling characteristics when in an aqueous environment, and polymeric materials which exhibit both swelling and gelling characteristics when in an aqueous environment.

159 (currently amended). A method according to claim 93 wherein the second release phase of the tablet further comprises at least one release retarding excipient which is selected from the group consisting of pH sensitive polymers, release-retarding polymers which exhibit swelling characteristics when in an aqueous environment, polymeric materials which exhibit gelling characteristics when in an aqueous environment, and polymeric materials which exhibit both swelling and gelling characteristics when in an aqueous environment.

160 (Currently amended). A method according to claim 103 wherein the second release phase of the tablet further comprises at least one release retarding excipient which is selected from the group consisting of pH sensitive polymers, release-retarding polymers which exhibit swelling characteristics when in an aqueous environment, polymeric materials which exhibit gelling characteristics when in an aqueous environment, and polymeric materials which exhibit both swelling and gelling characteristics when in an aqueous environment.

161 (previously presented). A method according to claim 156 wherein the at least one release retarding excipient is xanthan gum.

162 (previously presented). A method according to claim 158 wherein the at least one release retarding excipient is xanthan gum.

163 (previously presented). A method according to claim 159 wherein the at least one release retarding excipient is xanthan gum.

164 (previously presented). A method according to claim 160 wherein the at least one release retarding excipient is xanthan gum.

165 (previously presented). A method according to claim 161 wherein the xanthan gum is present in an amount from about 0.5% to about 8% by weight of the second release phase.

166 (previously presented). A method according to claim 163 wherein the xanthan gum is present in an amount from about 0.5% to about 8% by weight of the second release phase.

167 (previously presented). A method according to claim 161 wherein the xanthan gum is pharmaceutical grade xanthan gum, 200 mesh.

168 (previously presented). A method according to claim 163 wherein the xanthan gum is pharmaceutical grade xanthan gum, 200 mesh.

169 (previously presented). A method according to claim 165 wherein the xanthan gum is pharmaceutical grade xanthan gum, 200 mesh.

170 (previously presented). A method according to claim 13 wherein the pharmaceutically acceptable soluble salt of amoxicillin and the at least one pharmaceutically acceptable organic acid of the second release phase are admixed in intimate contact such that upon exposure to an aqueous environment they interact such that the rate of release of amoxicillin from the solid form of the second release phase is reduced compared to the rate of release of amoxicillin from the solid form of the first release phase.

171 (previously presented). A method according to claim 94 wherein the sodium amoxicillin and the at least one pharmaceutically acceptable organic acid of the second release phase are admixed in intimate contact such that upon exposure to an aqueous environment they interact such that the rate of release of amoxicillin from the solid form of the second release phase is reduced compared to the rate of release of amoxicillin from the solid form of the first release phase.

172 (previously presented). A method according to claim 103 wherein the crystallized sodium amoxicillin and the citric acid anhydrous acid of the second release phase are admixed in intimate contact such that upon exposure to an aqueous environment they interact such that the rate of release of amoxicillin from the solid form of the second release phase is reduced compared to the rate of release of amoxicillin from the solid form of the first release phase.

173 (previously presented). A method according to claim 13 wherein the composition has an in vitro dissolution profile such that about 45% to about 65% of the total amoxicillin is dissolved within 30 minutes, as determined by the <711> Dissolution Test, Apparatus 2, provided in USP 23, 1995, in 900 mL of deionized water, at a paddle speed of 75 rpm.

174 (previously presented). A method according to claim 103 wherein the composition has an in vitro dissolution profile such that about 45% to about 65% of the total amoxicillin is



dissolved within 30 minutes, as determined by the <711> Dissolution Test, Apparatus 2, provided in USP 23, 1995, in 900 mL of deionized water, at a paddle speed of 75 rpm.

175 (previously presented). A method according to claim 13 wherein the composition has an in vitro dissolution profile such that about 50% to about 75% of the total amoxicillin is dissolved within 60 minutes, as determined by the <711> Dissolution Test, Apparatus 2, provided in USP 23, 1995, in 900 mL of deionized water, at a paddle speed of 75 rpm.

176 (previously presented). A method according to claim 13 wherein the composition has an in vitro dissolution profile such that about 55% to about 85% of the total amoxicillin is dissolved within 120 minutes, as determined by the <711> Dissolution Test, Apparatus 2, provided in USP 23, 1995, in 900 mL of deionized water, at a paddle speed of 75 rpm.

177 (previously presented). A method according to claim 13 wherein the composition has an in vitro dissolution profile such that about 70% to about 95% of the total amoxicillin is dissolved within 180 minutes, as determined by the <711> Dissolution Test, Apparatus 2, provided in USP 23, 1995, in 900 mL of deionized water, at a paddle speed of 75 rpm.

178 (previously presented). A method according to claim 13 wherein the composition has an in vitro dissolution profile such that about 70% to about 100% of the total amoxicillin is dissolved within 240 minutes, as determined by the <711> Dissolution Test, Apparatus 2, provided in USP 23, 1995, in 900 mL of deionized water, at a paddle speed of 75 rpm.

179 (previously presented). A method according to claim 122 wherein the composition provides, a mean maximum plasma concentration ( $C_{max}$ ) of amoxicillin of at least 12 ug/mL.

180 (previously presented). A method according to claim 122 wherein the composition provides, a mean maximum plasma concentration ( $C_{\max}$ ) of amoxicillin of at least 16 ug/mL.

181 (previously presented). A method according to claim 122 wherein the composition provides, a mean plasma concentration of amoxicillin of at least 4 ug/mL for at least 4.4 hours.

182 (previously presented). A method according to claim 179 wherein the composition provides, a mean plasma concentration of amoxicillin of at least 4 ug/mL for at least 4.4 hours.

183 (previously presented). A method according to claim 122 wherein the composition provides, a mean plasma concentration of amoxicillin of at least 4 ug/mL for at least 4.8 hours.

184 (previously presented). A method according to claim 183 wherein the composition provides, a mean maximum plasma concentration ( $C_{\max}$ ) of amoxicillin of at least 16 ug/mL.

185 (previously presented). A method according to claim 122 wherein the composition provides an area under the curve (AUC) of the total amount of amoxicillin in the composition that is at least 80% of that of the corresponding dosage of amoxicillin taken as a immediate release formulation, over the same dosage period.

186 (previously presented). A method according to claim 122 wherein the composition provides an area under the curve (AUC) of the total amount of amoxicillin in the composition that is at least 90% of that of the corresponding dosage of amoxicillin taken as a immediate release formulation, over the same dosage period.

187 (previously presented). A method according to claim 122 wherein the composition provides an area under the curve (AUC) of the total amount of amoxicillin in the composition that is at least 100% of that of the corresponding dosage of amoxicillin taken as a immediate release formulation, over the same dosage period.

188 (previously presented). A method according to claim 122 wherein the composition provides an area under the curve (AUC) of the total amount of amoxicillin in the composition that is at least 110% of that of the corresponding dosage of amoxicillin taken as a immediate release formulation, over the same dosage period.

189 (previously presented). A method according to claim 122 wherein the composition provides an area under the curve (AUC) of the total amount of amoxicillin in the composition that is at least 120% of that of the corresponding dosage of amoxicillin taken as a immediate release formulation, over the same dosage period.

190 (previously presented). A method according to claim 122 wherein the composition provides an AUC,  $C_{\max}$ , and  $T_{\max}$  substantially according to Figure 5, profile A of Formulation VI.

191 (previously presented). A method according to claim 122 wherein the composition, provides an AUC,  $C_{\max}$ , and  $T > MIC$  substantially according to Figure 5, profile A of Formulation VI.

192 (previously presented). A method according to claim 122 wherein the composition provides an AUC,  $C_{\max}$ , and  $T_{\max}$  substantially according to Figure 5, profile B of Formulation VII.

193 (previously presented). A method according to claim 122 wherein the composition provides, an AUC,  $C_{max}$ , and  $T > MIC$  substantially according to Figure 5, profile B of Formulation VII.

194 (previously presented). A method according to claim 13 wherein the ratio of the pharmaceutically acceptable soluble salt of amoxicillin to the at least one pharmaceutically acceptable organic acid in the second release phase is about 1:1.

195 (previously presented). A method according to claim 71 wherein the ratio of amoxicillin in the first release phase to amoxicillin in the second release phase is about 9:7.

196 (previously presented). A method according to claim 194 wherein the ratio of amoxicillin in the first release phase to amoxicillin in the second release phase is about 9:7.

197 (previously presented). A method according to claim 86 wherein the citric acid is citric acid anhydrous.

198 (previously presented). A method according to claim 89 wherein the pharmaceutically acceptable soluble salt of amoxicillin is crystallized sodium amoxicillin.

199 (previously presented). A method according to claim 122 wherein the amount of amoxicillin administered is at a dosage regimen interval of about 12 hours.

200 (previously presented). A method according to claim 13 wherein the composition is administered at a dosage regimen interval of about 12 hours.

201 (previously presented). A method according to claim 109 wherein the amount of amoxicillin administered is at a dosage regimen interval of about 12 hours.

202 (previously presented). A method according to claim 111 wherein the amount of amoxicillin administered is at a dosage regimen interval of about 12 hours.

203 (previously presented). A method according to claim 114 wherein the amount of amoxicillin administered is at a dosage regimen interval of about 12 hours.

204 (cancelled).

205 (currently amended). A method for treating a bacterial infection in a patient, the method comprising

administering to the patient in need thereof a composition in solid dosage form comprising amoxicillin and potassium clavulanate, such that the amount of amoxicillin is about 2000mg and comprising a first release phase and a second release phase;

the first release phase comprising potassium clavulanate and a first portion of the amoxicillin;

the second release phase comprising a second portion of amoxicillin, which is a pharmaceutically acceptable soluble salt of amoxicillin, and at least one pharmaceutically acceptable organic acid selected from the group consisting of malonic acid, succinic acid, fumaric acid, maleic acid, adipic acid, lactic acid, levulinic acid, sorbic acid, tartaric acid, malic acid, ascorbic acid, and citric acid,

which are admixed in intimate contact at a ratio of from 20:1 to 1:2; such that the weight ratio of amoxicillin to potassium clavulanate is from 2:1 to 20:1, and the solid dosage is administered at a regimen interval of about 12 hours, and wherein the second release phase of the tablet further comprises at least one release retarding excipient which is selected from the group consisting of pH sensitive polymers, release-retarding polymers which exhibit swelling characteristics when in

an aqueous environment, polymeric materials which exhibit gelling characteristics when in an aqueous environment, and polymeric materials which exhibit both swelling and gelling characteristics when in an aqueous environment;

and wherein the solid dosage is such that the amount of amoxicillin released over thirty minutes is in the range about 45 to about 65% of the total amoxicillin content, over sixty minutes is in the range about 50 to about 75% of the total amoxicillin content, over two hours is in the range about 55 % to about 85% of the total amoxicillin content, over 180 minutes is in the range about 70 % to 95% of the total amoxicillin content and over 240 minutes is in the range about 70 to about 100% of the total amoxicillin content, as tested by the USP Dissolution Test, Apparatus 2, method at 37 degrees C, a paddle speed of 75 rpm and in 900 ml deionized water, over a period of 8 hours;

and which provides a mean maximum plasma concentration (Cmax) of at least 12 micrograms/ml and a mean time that the plasma concentration exceeds 4 micrograms/ml for at least 4.4 hours, when tested in a group of at least 7 healthy humans, based on blood sampling at half hourly intervals for the first two hours and thereafter at hourly intervals:

206 (previously presented). A method according to claim 18 wherein the bacterial infection is a respiratory tract infection.

207 (previously presented). A method according to claim 206 wherein the respiratory tract infection is community acquired pneumoniae (CAP), acute exacerbation of chronic bronchitis (AECB), or acute bacterial sinusitis (ABS).

208 (previously presented). A method according to claim 207 wherein the duration of treatment is from 7 to 14 days.

209 – 213 (cancelled).

214 (previously presented). A method according to claim 205 in which the bacterial infection is caused by at least one of the organisms *S. pneumoniae*, *H. influenzae*, and *M. catarrhalis*.

215 (previously presented). A method according to claim 214 wherein the *S. pneumoniae* are Drug Resistant *S. pneumoniae* and Penicillin Resistant *S. pneumoniae* organisms.

216 (previously presented). A method according to claim 214 wherein the bacterial infection is a respiratory tract infection.

217 (previously presented). A method according to claim 216 wherein the respiratory tract infection is community acquired pneumoniae (CAP), acute exacerbation of chronic bronchitis (AECB), or acute bacterial sinusitis (ABS).

218 (previously presented). A method according to claim 217 wherein the duration of treatment is from 7 to 14 days.

219 (previously presented). A method according to claim 93 wherein the composition is in the form of a bilayer tablet.

220 (previously presented). A method according to claim 130 wherein first release phase and the second release phase of the solid form composition is divided into multiple dosage form units, and the multiple dosage form units are compressed into a bilayer tablet.

221 (previously presented). A method according to claim 130 wherein the first release phase comprises at least one pharmaceutically acceptable soluble salt of amoxicillin, amoxicillin trihydrate, or a mixture thereof.

222 (previously presented). A method according to claim 221 wherein the amoxicillin is present in the second release phase is sodium amoxicillin.

223 (previously presented). A method according to claim 222 wherein the at least one pharmaceutically acceptable organic acid is selected from malonic acid, succinic acid, fumaric acid, maleic acid, adipic acid, lactic acid, levulinic acid, sorbic acid, tartaric acid, malic acid, ascorbic acid, or citric acid.

224 (previously presented). A method according to claim 223 wherein the at least one pharmaceutically acceptable organic acid is citric acid.

225 (previously presented). A method according to claim 166 wherein the at least one pharmaceutically acceptable organic acid is citric acid.

226 (previously presented). A method according to claim 225 wherein the first release phase comprises at least one pharmaceutically acceptable soluble salt of amoxicillin, amoxicillin trihydrate, or a mixture thereof.

227 (previously presented). A method according to claim 226 wherein the first release phase and the second release phase of the solid form composition is divided into multiple dosage form units.



228 (previously presented). A method according to claim 227 wherein the multiple dosage form units of the solid form composition are a compressed bi-layer tablet.

229 (previously presented). A method according to claim 140 wherein the multiple dosage form units of the solid form composition are a compressed bi-layer tablet.

230 (currently amended). A method according to claim 13 wherein the at least one pharmaceutically acceptable organic acid is selected from the group consisting of malonic acid, succinic acid, fumaric acid, maleic acid, adipic acid, lactic acid, levulinic acid, and sorbic acid.

231 (currently amended). A method according to claim 13 at least one pharmaceutically acceptable organic acid is selected from the group consisting of tartaric acid, malic acid, ascorbic acid, or citric acid, and an acidic salt thereof.

232 (currently amended). A method according to claim 71 wherein the at least one pharmaceutically acceptable organic acid is selected from the group consisting of malonic acid, succinic acid, fumaric acid, maleic acid, adipic acid, lactic acid, levulinic acid, and sorbic acid.

233 (currently amended). A method according to claim 71 at least one pharmaceutically acceptable organic acid is selected from the group consisting of tartaric acid, malic acid, ascorbic acid, citric acid, and an acidic salt thereof.

234 (currently amended). A method according to claim 81 wherein the at least one pharmaceutically acceptable organic acid is selected from the group consisting of malonic acid, succinic acid, fumaric acid, maleic acid, adipic acid, lactic acid, levulinic acid, and sorbic acid.

235 (currently amended). A method according to claim 81 at least one pharmaceutically acceptable organic acid is selected from the group consisting of tartaric acid, malic acid, ascorbic acid, citric acid, and an acidic salt thereof.